

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 23

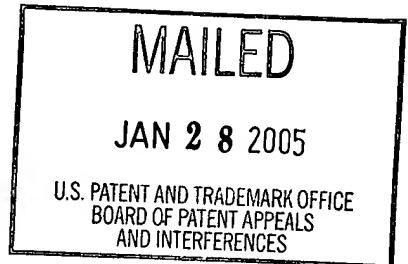
## UNITED STATES PATENT AND TRADEMARK OFFICE

### BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte SIMON F. WILLIAMS and DAVID P. MARTIN

Appeal No. 2004-1405  
Application No. 09/661,773

HEARD: November 18, 2004



Before SCHEINER, MILLS and GREEN, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

#### DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of claims 1-17 and 29-32, the only claims remaining in the application.

Claims 1, 2, 4, 15, 29, 31 and 32 are representative:

1. A composition for the repair or augmentation of tissue in an animal or human, comprising  
a biocompatible, bioabsorbable fluid which comprises a polyhydroxyalkanoate which is injectable into a human or animal for repair or augmentation of tissue.
2. The composition of claim 1 wherein the polyhydroxyalkanoate is a liquid or wax at a temperature between about 20 and 25°C.
4. The composition of claim 1 wherein the polyhydroxyalkanoate is a liquid at about 37°C.
15. The composition of claim 1 further comprising a bioactive agent.

29. A composition suitable for use in the treatment of osteoarthritic knees comprising

a biocompatible, bioabsorbable fluid which comprises a polyhydroxyalkanoate, wherein the composition is suitable for use as a viscosupplement.

31. A kit comprising

- (a) the composition of claim 1; and
- (b) a means for delivering the composition to a patient.

32. The kit of claim 31 wherein the means for delivering comprises a needle and a syringe.

The sole reference relied on by the examiner is:

Sankaram 6,277,413 Aug. 21, 2001

Claims 1-17 and 29-32 stand rejected under 35 U.S.C. § 102(e) as anticipated by Sankaram. We affirm the rejection with respect to claims 1, 15, 29, 31 and 32, but reverse with respect to claims 2-14, 16, 17 and 30.

#### BACKGROUND

"Polyhydroxyalkanoates (PHAs) are a class of naturally occurring polyesters that are synthesized by numerous organisms in response to environmental stress" (Specification, page 5). "PHA polymers may be broadly divided into three groups according to the length of their pendant groups and their respective biosynthetic pathways. Those with short pendant [acid] groups . . . are highly crystalline thermoplastic materials . . . A second group of PHAs contain[s] [short pendant acid groups] randomly polymerized with much longer pendant group hydroxy acid units" and "a third group of PHAs . . . contain[s] predominantly longer pendant group hydroxy acids" (*id.*, page 6).

"In all, about 100 different types of hydroxy acids have been incorporated into PHAs by fermentation methods so far . . . includ[ing] PHAs containing functionalized pendant groups such as esters, double bonds, alkoxy, aromatic, halogens and hydroxy groups" (id., page 7). "PHA polymers may also be derived by chemical synthesis" and "may contain varying amounts of the different hydroxy acid monomer types depending upon the specific properties [desired]" (id., page 8). "The viscosity of the liquid PHA polymers may be varied by changing the molecular weight of the polymer[s], crosslinking, and/or by changing the composition of the polymers" (id., page 9). "[I]t is also possible to use these methods to tailor bioabsorption rates" (id., page 10).

PHA polymers "suitable for repair of soft tissue, augmentation, and as viscosupplements . . . comprise liquid [PHA] polymer compositions or [PHA] microdispersions" (id., page 3). "In preferred embodiments, these [PHA] polymer compositions have low viscosities which enable them to be injected into soft tissue or the knee joint with a syringe and needle[,] . . . [they] preferably do not harden after implantation [and their] [d]egradation rates can be controlled so that [they] are slow to bioabsorb" (id.). "The PHA must be a fluid at body temperature or must be in the form of a microdispersion[ ] in a fluid carrier" (id., page 4).

"[T]he term 'bioabsorbable' refers to compositions which decompose[ ] under normal *in vivo* physiological conditions into components which can be metabolized or excreted. 'Slow bioabsorption' means that the composition performs the intended repair, augmentation, or viscosupplementation function for the appropriate time period, preferably longer than 1 month" (id.). "The term 'microdispersion' refers to a suspension of particles [which] form a separate phase from that of the continuous

phase [and] may be in an amorphous or crystalline state . . . [t]ypically, the particle size is on the order of 1 nm to 500  $\mu\text{m}$ " (*id.*). "The compositions preferably can be easily injected using . . . a syringe and needle, preferably one having a 16 gauge diameter . . . or [smaller]" (*id.*, page 5).

Finally, "[i]n one embodiment, the PHA is a wax at room temperature . . . which can be heated to body temperature or greater so that the composition liquifies, rendering it injectable. In a preferred embodiment, the PHA polymers are liquid polymers of [PHA] copolymers which do not crystallize at body temperature, [and] which bioabsorb slowly in vivo" (*id.*).

#### DISCUSSION

The examiner rejected claims 1-17 and 29-32 under 35 U.S.C. § 102(e) as anticipated by Sankaram. Claims 1, 15, 29, 31 and 32 represent the invention in its broadest aspect. Claim 1 is directed to an injectable biocompatible, bioabsorbable fluid composition comprising a polyhydroxyalkanoate, for repair or augmentation of tissue in a human or other animal. Claim 15 depends from claim 1, and further comprises a bioactive agent. Claim 29 is directed to an injectable biocompatible, bioabsorbable fluid composition comprising a polyhydroxyalkanoate, suitable for use as a viscosupplement. Claim 31 is directed to a kit containing the composition of claim 1 and means for delivering the composition for a patient; claim 32 depends from claim 31 and specifies that the means for delivery comprises a needle and syringe.

Appellants do not appear to dispute that Sankaram describes an injectable, biocompatible, bioabsorbable fluid comprising PHA polymer-lipid microspheres encapsulating a bioactive agent. Rather, appellants argue that Sankaram's composition is a pharmaceutical preparation for controlled release of the encapsulated

bioactive agent, and is not "suitable for use in soft tissue repair and augmentation or as [a] viscosupplement[ ]" because it does not "possess[ ] desirable physical properties, e.g., viscoelasticity, elasticity, pulpability, or flexibility, and chemical and biological properties which are critical attributes of PHA compositions having a certain type of PHA polymer of certain molecular weight in certain formulations" (Brief, page 11).

This argument is not persuasive with respect to claims 1, 15, 29, 31 and 32. The specification teaches that PHA polymer compositions "suitable for repair of soft tissue, augmentation, and as [a] viscosupplement[ ]" (Specification, page 3), preferably "have low viscosities which enable them to be injected into soft tissue or the knee joint with a syringe and needle[,] preferably do not harden after implantation [and their] [d]egradation rates can be controlled so that [they] are slow to bioabsorb" (id., emphasis added). The Specification further teaches that "[s]low bioabsorption' means that the composition performs . . . for [an] appropriate time period, preferably longer than 1 month" (id., page 4, emphasis added). The only absolute, or specifically defined, requirement is that the PHA must be "a fluid at body temperature or [ ] in the form of a microdispersion[ ] in a fluid carrier" (id.).

As discussed above, Sankaram describes an injectable biodegradable, bioabsorbable composition comprising polymer-lipid microspheres in a liquid carrier (i.e., PHAs in the form of a microdispersion in a fluid carrier). The present specification broadly describes preferred levels of biodegradability and bioabsorbability, but does not provide defined parameters. There is simply nothing definitive in claims 1, 15, 29, 31 or 32, even when read in light of the specification, that distinguishes those compositions from Sankaram's compositions.

With respect to the lipid in Sankaram's compositions, appellants assert that "lipid undergoes rapid metabolism upon administration to a patient and is rapidly absorbed"<sup>1</sup> – inasmuch as "it is not desirable that materials to be used in soft tissue repair and augmentation and as viscosupplements [ ] be metabolized or absorbed rapidly . . . the composition of Sankaram" does not anticipate the claimed invention (Brief, page 12). We do not find this argument to be persuasive inasmuch as the present specification teaches that lipids may be used in the claimed composition "to increase the safety and efficacy of the composition" (Specification, page 11).

Nor are we persuaded by appellants' argument that Sankaram's composition contains organic solvent, "a material which is expressly not allowed for tissue augmentation" (Reply Brief, page 7). First, Sankaram expressly states that "volatile organic solvent" used in forming the polymer-lipid microspheres "is substantially or completely removed" (column 10, lines 20-25), thus "[t]he [final] composition is substantially free of volatile organic solvent" (column 2, lines 64-65). Appellants have provided no evidence that volatile organic solvents are not permitted in tissue augmentation compositions under these circumstances. Second, we note that Example 6 of the specification uses chloroform, a volatile organic solvent, to extract PHA polymers from recombinant E. coli.

We find that the examiner has established a prima facie case of anticipation for claims 1, 15, 29, 31 and 32, which appellants have not overcome by argument or evidence. Accordingly, we affirm the rejection under 35 U.S.C. § 102(e) with respect to these claims.

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<sup>1</sup> Appellants cite Weinstock et al. (J. Lipid Res., Vol. 38, No. 9, pp. 1782-1794 (1997)) in support of this assertion, but this reference does not appear to be of record.

Claims 2-14, 16, 17 and 30<sup>2</sup> stand on a different footing. Without belaboring the record, we will simply say that the examiner has identified nothing in Sankaram which describes the specific limitations of these claims. Merely by way of example, we note that Sankaram teaches that "the biodegradable polymer and the lipid form[ ] the boundaries of [microspheres]" (column 10, lines 57-59), but the examiner does not point to any evidence that Sankaram's polymer exists in the form of a liquid or wax between about 20 and 25°C (claim 2), or that they are liquid at body temperature (claim 3). Certainly, we see no mention of the particular monomers required by claim 10.

We find that the examiner has not established a prima facie case of anticipation with respect to claims 2-14, 16, 17 and 30, and we reverse the rejection with respect to these claims.

#### CONCLUSION

The rejection of the claims under 35 U.S.C. § 102(e) as anticipated by Sankaram is affirmed with respect to claims 1, 15, 29, 31 and 32, but reversed with respect to claims 2-14, 16, 17 and 30.

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<sup>2</sup> Claim 30 appears to depend from a cancelled claim.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

*Toni R. Scheiner*

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